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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/630,355
Filing Date: July 30, 2003
Appellant(s): MOMMA ET AL.

John Cunniff
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 6/14/07 appealing from the Office action mailed 11/16/06.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6,254,632	**Wu et al.**	**7-2001**
6,287,628	**Hossainy et al.**	**9-2001**

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1,3-13,26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wu et al. (6254632). Wu et al. disclose (Fig. 2B) a stent having a base body with a plurality (col. 8, lines 50-56) of microdevices **200** that project from the implant surface to form a microcannula **218** on the outer surface to engage the vessel wall, col. 6, lines 13-17. Wu also discloses the thickness of the cover is from 25-500μm, col. 9, lines 13,14. Wu additionally discloses that the protrusions or "microcannulae" can extend out of the cover to penetrate into tissue, col. 9, lines 17-19. Regarding the limitation of "when the implant bears in surface contact against a wall of the blood vessel, the microcannula penetrates into the media.." the Examiner interprets this limitation such that the structure only needs to perform or be capable of the intended use. Wu discloses a range that overlaps the claimed range but not the specifics claimed that fall within the prior art range, specifically between 10-400μm. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have a height of a protrusion or "micorcannulae dimension that falls within the claimed range of 100 to about 400μm since it would need to have a dimension long enough in order to protrude through the cover having the thickness range between if it were 300 to 500μm as disclosed by Wu, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. Fig. 4A shows a cover layer **420** of

biodegradable material (col. 6, lines 33-42) that closes the active substance **410** in the deposit. The microdevices are fully capable of being applied using hybrid technology. Wu additionally discloses the active substance is liberated once the stent is implanted and the microcannulae engage the vessel wall, col. 6,lines 18-26. Wu discloses the stent can be made from a biodegradable material and from a magnesium alloy, col. 4, lines 43,44,47,48,54. Thus, a 300μm cover and a 400μm microcannula results in a structure that would be capable of penetrating the media since Wu discloses it is desirable to penetrate the vessel (col. 9, line 19), but not specifically the media. However, since the microcannula can be the same length as claimed, it must be able to perform the function since the media would inherently be a layer present in the patient's vessel wall structure.

With respect to claims 3,4 Wu does disclose the lengths or depths of the microcannulae can be any dimension depending on the amount of drug desired to be delivered, col. 6, lines 61-66. However, Wu fails to disclose the lengths of the microcannulae to be 180μm-250μm. It would have been an obvious matter of design choice to modify the length of the microcannulae, since applicant has not disclosed that using a length of 150μm or 180μm provides any advantage, or solves a stated problem, or is used for any particular purpose. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the length taught by Wu et al. or the claimed lengths in claim(s) 3,4 because both stents perform the same function of delivering a therapeutic substance to a vessel and anchoring the stent in the wall.

Claims 14,15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wu et al. '632 in view of Hossainy et al. (6287628). Wu et al. is explained supra. However, Wu fails to disclose the use of a biodegradable drug carrier to hold the active substance. Hossainy et al. teach that impregnated polymers can be used to hold therapeutic materials to place in the microcannulae (col. 9, lines 21-25) and that biodegradable carriers can be used, col. 10,lines 50-52,57-59. It would have been obvious to one of ordinary skill in the art to use a biodegradable carrier to hold the drug and fill the microcannulae as taught by Hossainy in the stent of Wu et al. such that it degrades over time and has a controlled release rate at the implantation site.

(10) Response to Argument

A. Applicant begins by stating the Examiner has the burden of establishing a *prima facie* case of obviousness and not use hindsight. The Examiner recognizes this and in response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In this case, the patent relied upon discloses the issues of placing a stent in a vessel and how to achieve this. Stents are basically classified under two categories, 1) self-expanding 2) balloon expandable, but both types involve a force applied to the stent which then imparts a

force against the vessel wall. Wu discloses that the projecting microcannula structure, see Figs. 4Aa, 4B for an illustration are there to project and anchor into the vessel wall (col. 9, line 19) and even aid in the delivery of the drug while preventing loss of the drug (col. 6, lines 21-24). Thus, the basic knowledge of the invention is disclosed in Wu and it would only involve routine skill in the art to perfect or determine what length of the microcannula provides the optimal results of effectively delivering the drug and not losing it into the blood flow.

B. 1) Applicant then argues that in establishing a *prima facie* case of obviousness there must be a motivation to combine. In this case, the Examiner was not combining any references for claim 1, but modifying the reference to conclude a narrower, specific range was obvious in view of a broader range disclosed in the prior art. Wu discloses the stent protrusion or microcannula can penetrate the cover and into the vessel. Wu gives (col. 9, lines 13,14) the dimension of the cover to be 25-500μm and thus if a microcannula is to penetrate through the cover into the vessel wall it must be of a greater length than the cover. Applicant claims a length of the microcannula to be 100-400μm of which falls in the range disclosed by Wu. Thus if a cover was 99-399μm (which falls in the range disclosed by Wu) then a microcannula must be 100-400μm to be able to extend out of the cover into the vessel as stated by Wu, col. 9, lines 18,19. 2) Applicant then argues there must be expectation of success for the modification. Clearly, every patient will not necessarily have the same anatomical dimensions and a doctor must assess the condition of the patient and determine an optimum size or dimension to use. It is definitely predictable that if the cover is thicker than the

dimensions of the microcannula must be longer or greater in height to penetrate through the cover into the vessel wall. 3) Applicant does not state what is lacking.

C. 1) Applicant argues that Wu does not have the microcannula engage the media to deliver an active substance into the media, but are just to engage and secure the stent to the vessel, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). However, Wu indeed discloses that the active substance is intended to be released into the media when the microcannula secure the stent to the wall, see col. 6, lines 21-26. Thus, it would have been obvious in view of Wu's disclosure to find the optimal microcannula length to increase the amount of therapeutic substance delivered into the vessel and reduce or eliminate any loss to blood flow. 2) Applicant states there is no motivation to modify the Wu device, but it is well known that drugs, pharmaceutical agents, therapeutic substances can be costly or expensive. As mentioned above, Wu discloses the desire to increase the drug delivered to the site of treatment and prevent loss. It would be an obvious expedient to increase the effectiveness in delivering the agent to the site to reduce a cost of having to retreat a patient with a drug solely because it did not get delivered to the treatment site. This is implied clearly by Wu's teaching that an increase in the amount of drug delivered to the site is advantageous and one of ordinary skill would accomplish this by finding the optimal length of the microcannula on the stent to ensure it stays or remains secured or attached to the vessel wall, col. 9, lines 21-26.

3) In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., that the delivery of the device and active substance does not address or deal with restenosis problems) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). It should be noted that Wu clearly discloses drugs or agents to treat restenosis, see col. 7, lines 3-67 of Wu. The Applicant also argues there is no expectation of success in modifying Wu's length of the microcannula. However, since Wu discloses a range that covers the Applicant's range, finding the specifics as claimed is advantageous to the success of delivering the agent.

D) In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Thus, Hossainy provides an alternative delivery means to place the agent in the depot. This would allow the length of the microcannula to be optimized also in that the depot would not include separate layers of drug and polymer, but a single layer of drug and polymer combined and allow the length to be adjusted taking into consideration that a single layer would take up less space. Thus it is proper to combine.

In conclusion of taking the reference as a whole the teachings provide the basis for the modification and finding the optimal length of the microcannula.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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